

Whole Food Supplements

November 15, 2001

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The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- 1. The Protomorphogen[™] brand extracts found in both Symplex F & M enhance the healthy functioning of the human adrenal, thyroid, and pituitary glands, and reproductive organs.
- 2. Collectively, these glands promote appropriate hormone production to help regulate cardiovascular and muscle function, enhance central nervous system response to daily stress, encourage healthy energy production and basal metabolism rate, and promote protein synthesis.
- 3. The ingredients found in Symplex M are combined specifically to address the unique demands of the male body.

These statements are made for a dietary supplement containing a proprietary blend of magnesium citrate, bovine orchic PMGTM extract, bovine adrenal PMGTM extract, bovine pituitary PMGTM extract, and bovine thyroid PMGTM extract (processed to remove its thyroxine). Other ingredients include calcium lactate, cellulose, and calcium stearate. The name of the product is Symplex® M.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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